

## II. REMARKS

### Formal Matters

Claims 20-34 are pending after entry of the amendments set forth herein.

Claims 20-35 were examined and were rejected.

Claims 20, 26, and 32 are amended. The amendments to the claims were made solely in the interest of expediting prosecution, and are not to be construed as an acquiescence to any objection or rejection of any claim. Claim 26 is amended to change the claim dependency. Support for the amendments to claims 20, 26, and 32 is found in the claims as originally filed, and throughout the specification, in particular at the following exemplary locations: claim 20: page 6, lines 6-13; and page 13, lines 5-22; claim 32: page 26, line 10. Accordingly, no new matter is added by these amendments.

Claim 35 is canceled without prejudice to renewal, without intent to acquiesce to any rejection, and without intent to surrender any subject matter encompassed by the canceled claim. Applicants expressly reserve the right to pursue any canceled subject matter in one or more continuation and/or divisional applications.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

### Allowable subject matter

Applicants note with gratitude that claim 35 would be allowable if rewritten to overcome the rejection under 35 U.S.C. §112, first paragraph, and to include all of the limitations of the base claim and any intervening claims.

### Rejections under 35 U.S.C. §112, first paragraph

Claims 20-34 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement and adequate written description. Claim 35 was rejected under 35 U.S.C. §112, first paragraph, as allegedly not enabled.

### Claims 20-34; enablement, written description

The Office Action stated that the instant specification is not enabling for the full breadth of the instant claims because it does not provide an adequate written description of the genus of nucleic acid molecules that are encompassed by “a recombinant nucleic acid comprising a nucleotide sequence that

encodes a biologically active capsaicin receptor polypeptide." Applicants respectfully traverse the rejection.

*Written description*

The Office Action stated that although the instant specification provides a detailed description of a number of recombinant nucleic acids encoding particular mammalian capsaicin receptors having very specific physical and structural properties, the instant specification does not provide a structural formula which is definitive of all capsaicin receptors.

The written description requirement of 35 U.S.C. §112, first paragraph, requires only that the specification describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.<sup>1</sup> As stated in the Revised Guidelines, possession may be shown in any number of ways, including by actual reduction to practice. The Office Action acknowledged that Applicants provided a detailed description of a number of recombinant nucleic acids encoding particular mammalian capsaicin receptors. By providing a detailed description of a number of recombinant nucleic acids encoding particular mammalian capsaicin receptors, Applicants demonstrated actual reduction to practice. Accordingly, Applicants were in possession of the claimed invention.

The Revised Guidelines also state that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice. As noted above, Applicants provided description of nucleic acids comprising nucleotide sequences encoding capsaicin receptors from a number of mammalian species. Applicants also provided description of nucleic acids comprising nucleotide sequences encoding capsaicin receptors from a non-mammalian species (e.g., chicken). Applicants submit that a representative number of species has been disclosed.

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<sup>1</sup> The Revised Interim Guidelines for Examination of Patent Applications Under 35 U.S.C. §112, paragraph 1 "Written Description" Requirement, (*Federal Register* (Dec. 21, 1999) Vol. 64 (No. 244):71427-71440) ("Revised Guidelines").

*Enablement*

The enablement requirement of 35 U.S.C. §112, first paragraph, requires that Applicants teach how to make and use the claimed invention.

Applicants have provide ample description of how to carry out a method of screening an agent that modulates capsaicin receptor function, the method comprising combining a candidate agent with a eukaryotic cell (as recited in claim 20) that expresses capsaicin receptor polypeptide on the cell surface; and determining the effect of the agent on capsaicin receptor function. Specification, page 23, line 23 to page 27, line 6. The specification provides ample description of how to determine the effect of an agent on capsaicin receptor function, including, e.g., by assaying levels of intracellular cations (page 26, lines 1-5; and page 26, line 29 to page 27 line 6), by assaying ligand-activated conductances (page 26, lines 5-6), by assaying an electrophysiological response (page 26, lines 7-8), by assaying calcium-induced reporter gene expression (page 26, line 10), etc. The specification further provides working examples of assays for capsaicin receptor function. Specification, e.g., Example 1, page 41, line 1 to page 42, line 9; Example 5, page 45, lines 1-29; Example 6, page 45, line 31 to page 48, line 27; and Example 8, page 49, line 20 to page 50, line 8. Accordingly, the specification is in compliance with the enablement requirement of 35 U.S.C. §112, first paragraph.

In view of the above discussion, claims 20-34 fulfill the written description and enablement requirements of 35 U.S.C. §112, first paragraph. Nevertheless, and solely in the interest of expediting prosecution, claim 20 is amended to recite “wherein said capsaicin receptor is encoded by a polynucleotide that hybridizes under stringent hybridization conditions to the complement of a polynucleotide having the sequence set forth in SEQ ID NO:1.” Applicants note for the record that the term “polynucleotide” as used in the instant application, includes single- and double-stranded DNA or RNA, and therefore “a polynucleotide that hybridizes under stringent hybridization conditions to the complement of a polynucleotide having the sequence set forth in SEQ ID NO:1” is equivalent to “a polynucleotide that hybridizes under stringent hybridization conditions to a polynucleotide having the sequence set forth in SEQ ID NO:1.”

Claim 35; enablement

The Office Action stated that claim 35 requires a nucleic acid to encode a mammalian capsaicin receptor and to hybridize under stringent conditions to a nucleic acid that also encodes a capsaicin

receptor. The Office Action stated that the specification does not provide guidance to produce a nucleic acid which encodes a capsaicin receptor in both its sense and antisense directions.

Claim 35 is canceled without prejudice to renewal, thereby rendering the rejection of this claim moot.

Conclusion as to the rejections under 35 U.S.C. §112, first paragraph

Applicants submit that the rejection of claims 20-34 under 35 U.S.C. §112, first paragraph, has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejection under 35 U.S.C. §112, second paragraph

Claims 26, 27, 29, and 32 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite.

Claims 26, 27, and 29

The Office Action stated that claim 26 is vague and indefinite because there is no antecedent basis for “the response.”

Claim 26 is amended to depend from claim 24, which provides antecedent basis for “the response.”

The Office Action stated that claim 32 is incomplete for omitting an essential element. The Office Action stated that it is unclear how one can measure calcium-induced reporter gene expression when the claim does not require the presence of a calcium-inducible reporter gene.

Without conceding as to the correctness of this rejection, claim 32 is amended to recite “wherein said cell further comprises a reporter gene operably linked to a calcium inducible promoter, and wherein said determining is by measuring calcium-induced expression of the reporter gene.”

Applicants submit that the rejection of claims 26, 27, 29, and 32 under 35 U.S.C. §112, second paragraph, has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.


### III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCSF084CON.

Respectfully submitted,  
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Date: Oct. 30, 2003

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